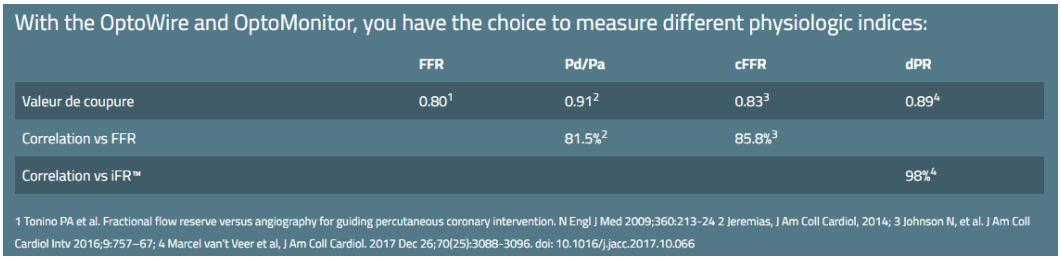
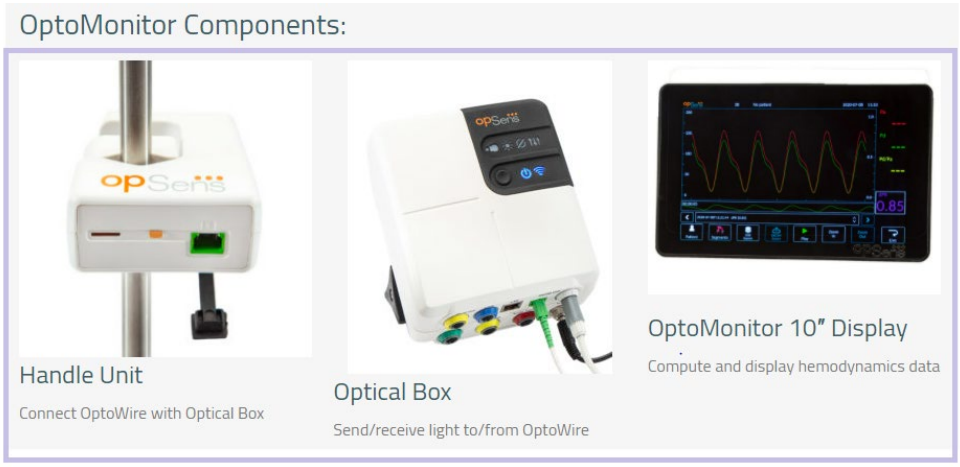
Exhibit D

Accused Products: System Including (Method Using) at Least OptoWire and OptoMonitor And Accompanying Auxiliary Products		
U.S. 10,912,463 (Davies '463)		
Exemplary Claim	Claim Terms in US 10,912,463	Representative Evidence from Defendants
1[pre]	A system for evaluating a stenosis of a vessel of a patient, the system comprising:	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a system for evaluating assessing a stenosis of a vessel of a patient. Exemplary public evidence includes the following excerpts from OpSens' website: OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries. OptoWire is powered by Fidela™, a patented 2nd generation fiber optic sensor to measure physiologic indices including Fractional Flow Reserve (FFR and diastolic Pressure Ratio (dPR). ▸ MORE INFORMATION https://opsensmedical.com/products/optowire/ With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices: FFR: Valeur de coupure 0.80[1]; Correlation vs FFR —; Correlation vs iFR™ — Pd/Pa: Valeur de coupure 0.91[2]; Correlation vs FFR 81.5%[2]; Correlation vs iFR™ — cFFR: Valeur de coupure 0.83[3]; Correlation vs FFR 85.8%[3]; Correlation vs iFR™ — dPR: Valeur de coupure 0.89[4]; Correlation vs FFR —; Correlation vs iFR™ 98%[4] 1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066 https://opsensmedical.com/products/optomonitor/

		"5.6 INDICATIONS FOR USE To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease." *OpSens Submission for FDA Approval*, Complaint Exhibit C, p. 5.
1[a]	A pressure-sensing guide wire sized and shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure monitoring element coupled to the distal portion;	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a pressure-sensing guide wire sized and shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure monitoring element coupled to the distal portion. Exemplary public evidence includes the following excerpts from OpSens' website:  "OptoWire OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries."

		 https://opsensmedical.com/products/optowire/ "The OptoWire III was then reconnected to the OptoMonitor and post-PCI physiology repeated with an increase in resting dPR to 0.97, indicating no residual flow limitation. The OptoWire III was withdrawn to the tip of the guide catheter, an absence of pressure drift confirmed, and the wire and guiding catheter removed. The patient was symptom-free and in stable condition at the procedure end." https://www.hmpgloballearningnetwork.com/site/cathlab/content/opsens-optowire-iii-next-generation-workhorse-pressure-guidewire
1[b]	A processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument, the processing unit configured to:	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise A processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument. Exemplary public evidence includes the following excerpts from OpSens' website:

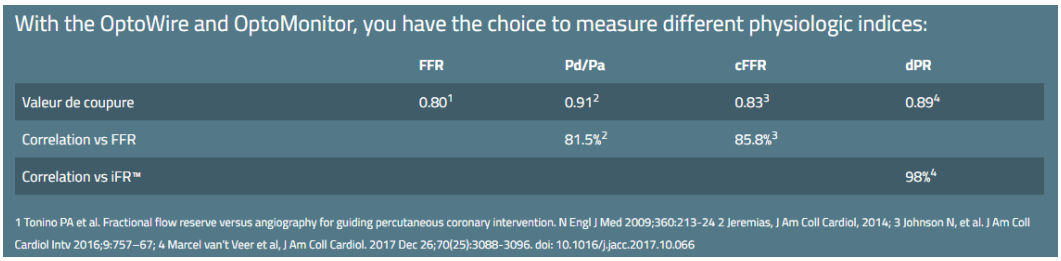
		 "The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system."   https://opsensmedical.com/products/optomonitor/
1[c]	Receive proximal pressure measurements obtained by the pressure-sensing instrument during a	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to receive proximal pressure measurements obtained by the pressure-sensing instrument during a cardiac cycle of the patient, wherein the proximal pressure measurements are obtained without application of a hyperemic agent to the patient. Exemplary public evidence includes the following excerpts from OpSens' website:

	cardiac cycle of the patient, wherein the proximal pressure measurements are obtained without application of a hyperemic agent to the patient;			

DPR	Diastolic pressure ratio	Average Pd/Pa during the entire diastole	Generic—Opsens, Acist (?)
dPR	Diastolic pressure ratio	Pd/Pa during the flat period of the dP/dt signal (the wave-free period)	Generic—Erasmus MC/ Rotterdam

See https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.

"The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system."



With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices:

	FFR	Pd/Pa	cFFR	dPR
Valeur de coupure	0.80[1]	0.91[2]	0.83[3]	0.89[4]
Correlation vs FFR		81.5%[2]	85.8%[3]	
Correlation vs iFR™				98%[4]

1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066

https://opsensmedical.com/products/optomonitor/

"dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio).

iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively.

The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping."

Opsens Submission for FDA Approval, see Complaint Exhibit C at p. 5.

<table>
<tr><td></td><td></td><td>“dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device).”

Opsens Submission for FDA Approval, see Complaint Exhibit C at p. 7.</td></tr>
<tr><td>1[d]</td><td>Receive distal pressure measurements obtained by the pressure monitoring element of the pressure-sensing guide wire during the cardiac cycle of the patient, wherein the distal pressure measurements are obtained without the application of the hyperemic agent to the patient;</td><td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to receive distal pressure measurements obtained by the pressure monitoring element of the pressure-sensing guide wire during the cardiac cycle of the patient, wherein the distal pressure measurements are obtained without the application of the hyperemic agent to the patient. Exemplary public evidence includes the following excerpts from OpSens’ website:

<table>
<tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr>
<tr><td>dPR</td><td>Diastolic pressure ratio</td><td>Pd/Pa during the flat period of the dP/dt signal (the wave-free period)</td><td>Generic—Erasmus MC/ Rotterdam</td></tr>
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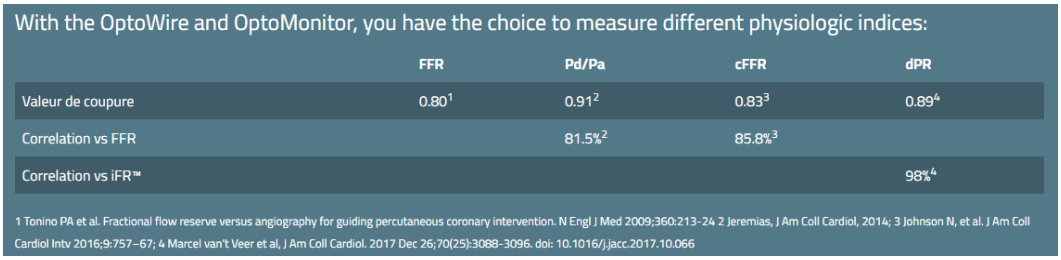
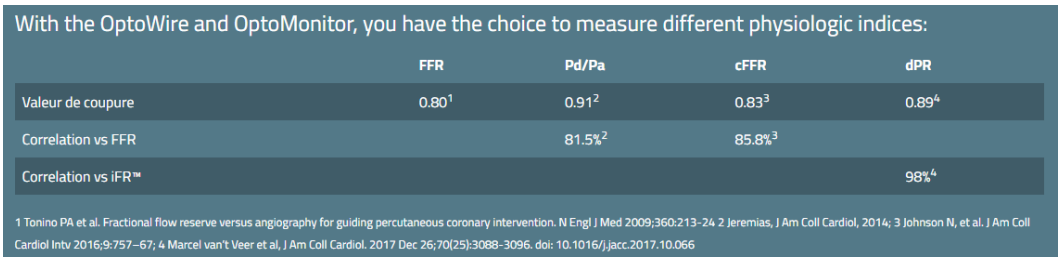
“The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system.”

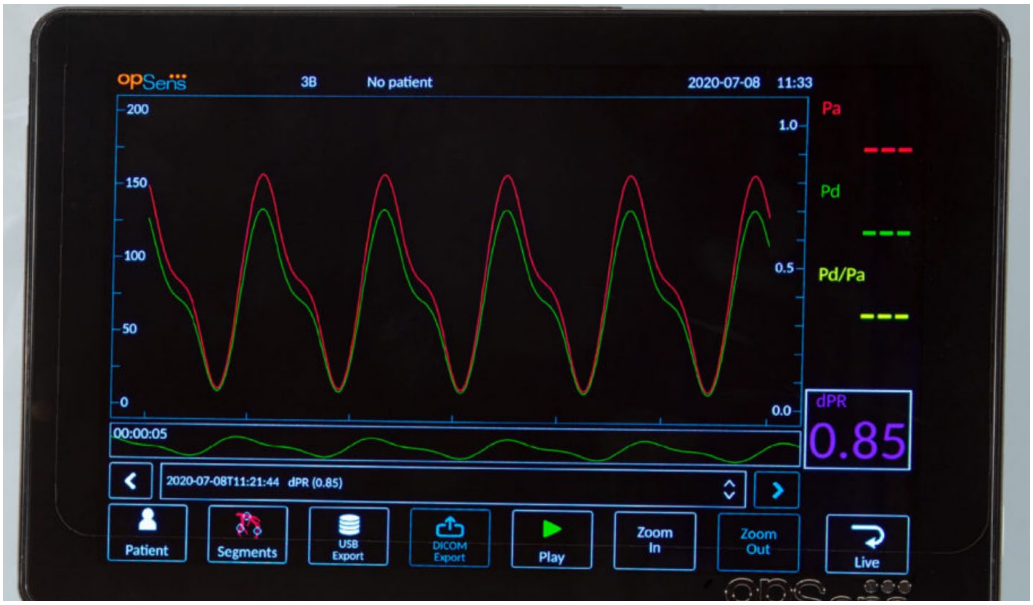


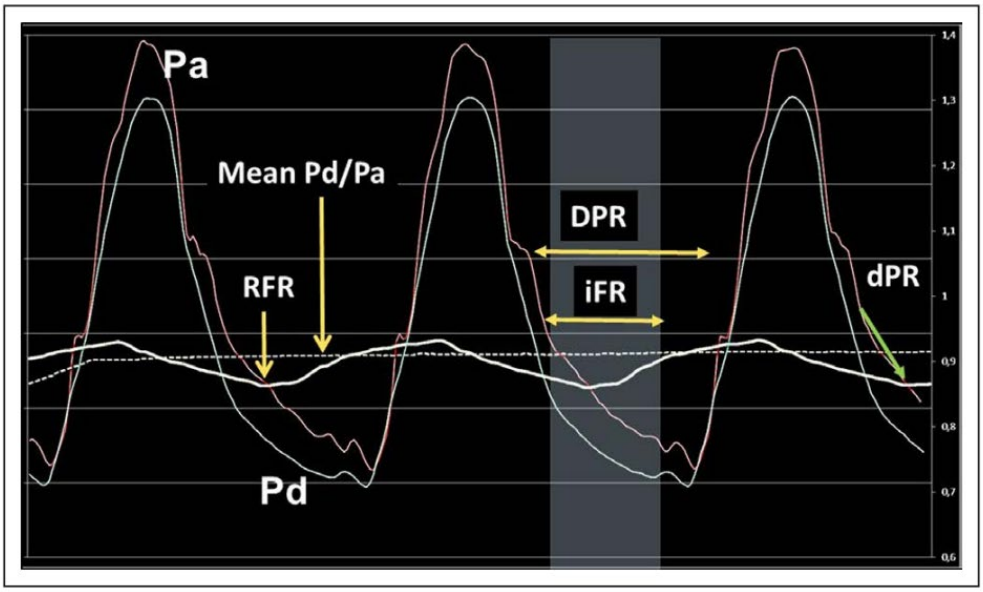
https://opsensmedical.com/products/optomonitor/

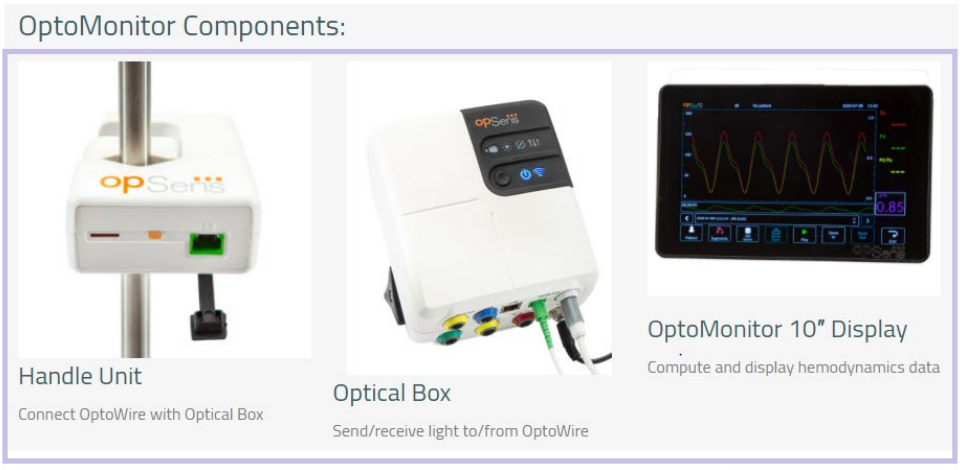
“dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the</td></tr>
</table>

		diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 5. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
1[e]	Select a diagnostic window within the cardiac cycle of the patient, wherein a starting point of the diagnostic window is determined based on at least one of the received proximal	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to select a diagnostic window within the cardiac cycle of the patient, wherein a starting point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient. Exemplary public evidence includes the following excerpts from OpSens' website:

	pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient;	<table><tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr><tr><td>dPR</td><td>Diastolic pressure ratio</td><td>Pd/Pa during the flat period of the dP/dt signal (the wave-free period)</td><td>Generic—Erasmus MC/ Rotterdam</td></tr></table> *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540. "The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system."  https://opsensmedical.com/products/optomonitor/ "dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 5.

		"dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
1[f]	Calculate a pressure ratio based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window; and	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to calculate a pressure ratio based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window. Exemplary public evidence includes the following excerpts from OpSens' website:  https://opsensmedical.com/products/optomonitor/ | DPR | Diastolic pressure ratio | Average Pd/Pa during the entire diastole | Generic—Opsens, Acist (?) | | dPR | Diastolic pressure ratio | Pd/Pa during the flat period of the dP/dt signal (the wave-free period) | Generic—Erasmus MC/ Rotterdam |

		See https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.  *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540 (annotation in original). "dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 6. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over

		the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
1[g]	Output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patent,	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patent. Exemplary public evidence includes the following excerpts from OpSens' website:   https://opsensmedical.com/products/optomonitor/

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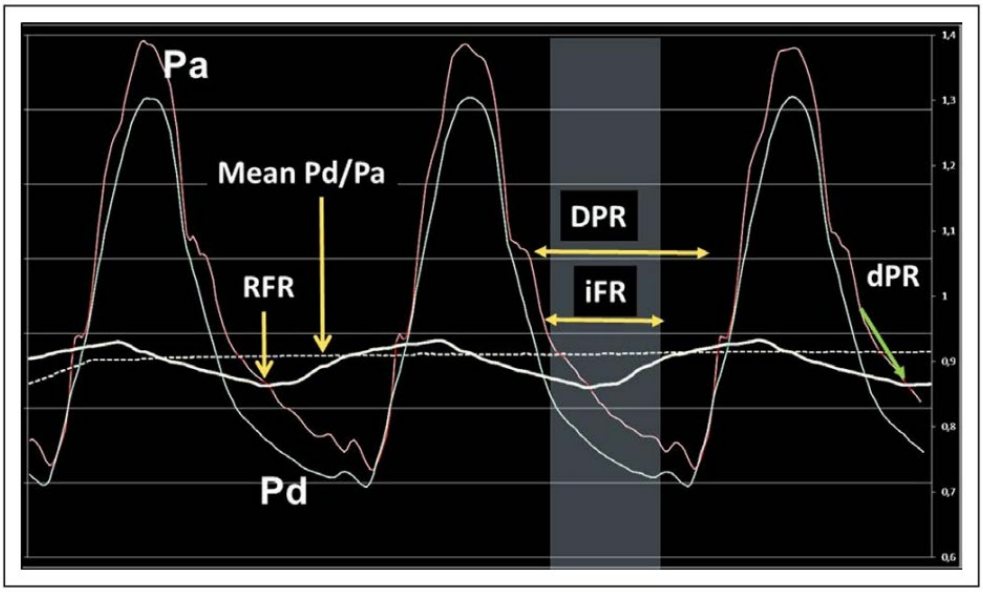
1[h]	Wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window.	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, calculate a pressure ratio as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window. Exemplary public evidence includes the following excerpts from OpSens' website:  https://opsensmedical.com/products/optomonitor/ <table><tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr><tr><td>dPR</td><td>Diastolic pressure ratio</td><td>Pd/Pa during the flat period of the dP/dt signal (the wave-free period)</td><td>Generic—Erasmus MC/ Rotterdam</td></tr></table>

		See https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.  *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540 (annotation in original). "dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 6. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over

		the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.

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<tr>
<td>11[pre]</td>
<td>A system for evaluating a stenosis of a vessel, the system comprising:</td>
<td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a system for evaluating assessing a stenosis of a vessel. Exemplary public evidence includes the following excerpts from OpSens' website:

OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries.

OptoWire is powered by Fidela™, a patented 2nd generation fiber optic sensor to measure physiologic indices including Fractional Flow Reserve (FFR and diastolic Pressure Ratio (dPR).

▸ MORE INFORMATION

https://opsensmedical.com/products/optowire/

With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices:

<table>
<tr><th></th><th>FFR</th><th>Pd/Pa</th><th>cFFR</th><th>dPR</th></tr>
<tr><td>Valeur de coupure</td><td>0.80[1]</td><td>0.91[2]</td><td>0.83[3]</td><td>0.89[4]</td></tr>
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1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066

https://opsensmedical.com/products/optomonitor/

"5.6 INDICATIONS FOR USE

To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease."

OpSens Submission for FDA Approval, Complaint Exhibit C, p. 5.</td>
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<tr>
<td>11[a]</td>
<td>a pressure-sensing guide wire sized and</td>
<td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a pressure-sensing guide wire sized and shaped for introduction into the vessel of</td>
</tr>
</table>

	shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure-monitoring element coupled to the distal portion;	the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure-monitoring element coupled to the distal portion. Exemplary public evidence includes:  "OptoWire OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries."  https://opsensmedical.com/products/optowire/ "The OptoWire III was then reconnected to the OptoMonitor and post-PCI physiology repeated with an increase in resting dPR to 0.97, indicating no residual flow limitation. The OptoWire III was withdrawn to the tip of the guide

		catheter, an absence of pressure drift confirmed, and the wire and guiding catheter removed. The patient was symptom-free and in stable condition at the procedure end." https://www.hmpgloballearningnetwork.com/site/cathlab/content/opsens-optowire-iii-next-generation-workhorse-pressure-guidewire
11[b]	a processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument, the processing unit configured to:	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument. Exemplary public evidence includes the following excerpts from OpSens' website:  "The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system." With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices: | | FFR | Pd/Pa | cFFR | dPR | | --- | --- | --- | --- | --- | | Valeur de coupure | 0.80[1] | 0.91[2] | 0.83[3] | 0.89[4] | | Correlation vs FFR | | 81.5%[2] | 85.8%[3] | | | Correlation vs iFR™ | | | | 98%[4] | 1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066

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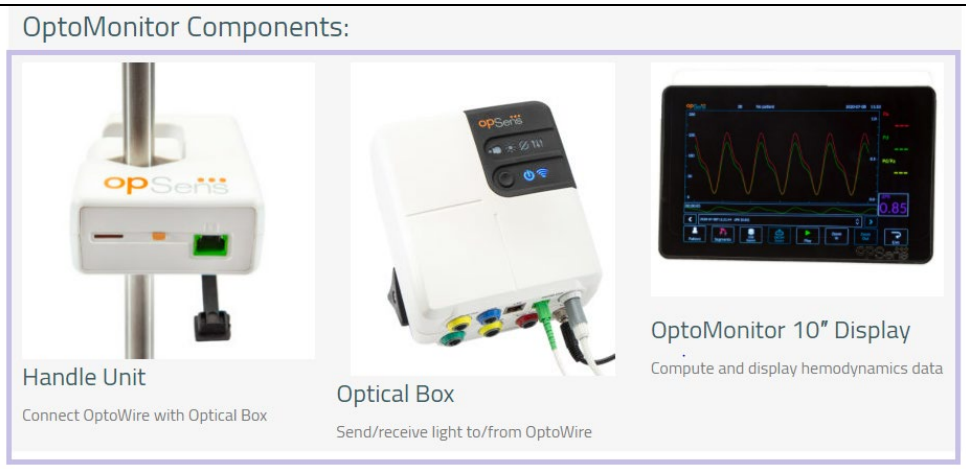

https://opsensmedical.com/products/optomonitor/</td></tr>
<tr><td>11[c]</td><td>receive proximal pressure measurements and distal pressure measurements, wherein the proximal and distal pressure measurements are respectively obtained by the pressure-sensing instrument and the pressure-sensing guide wire without application of a hyperemic agent to the patient;</td><td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to receive proximal pressure measurements and distal pressure measurements, wherein the proximal and distal pressure measurements are respectively obtained by the pressure-sensing instrument and the pressure-sensing guide wire without application of a hyperemic agent to the patient. Exemplary public evidence includes:
<table>
<tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr>
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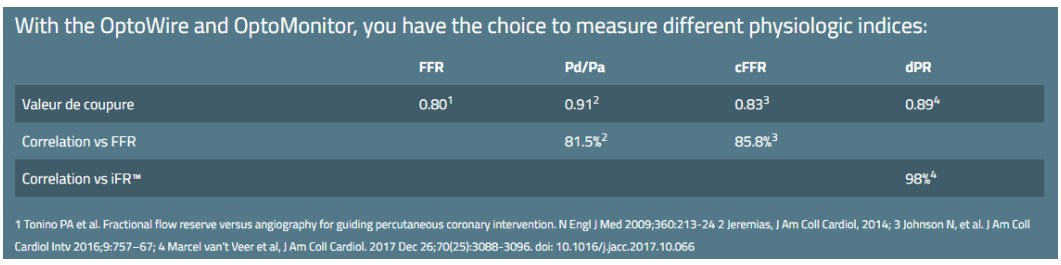
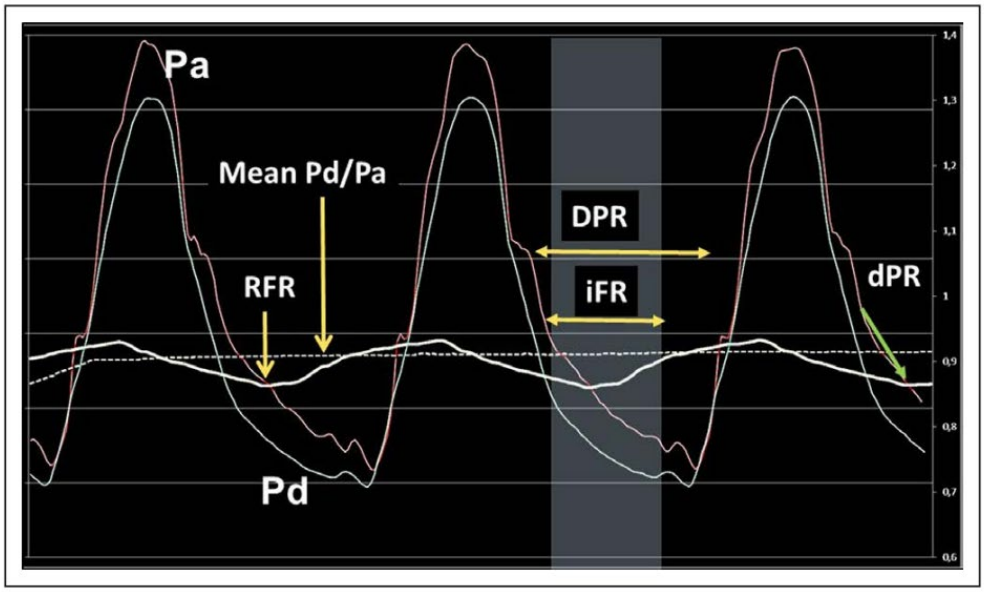
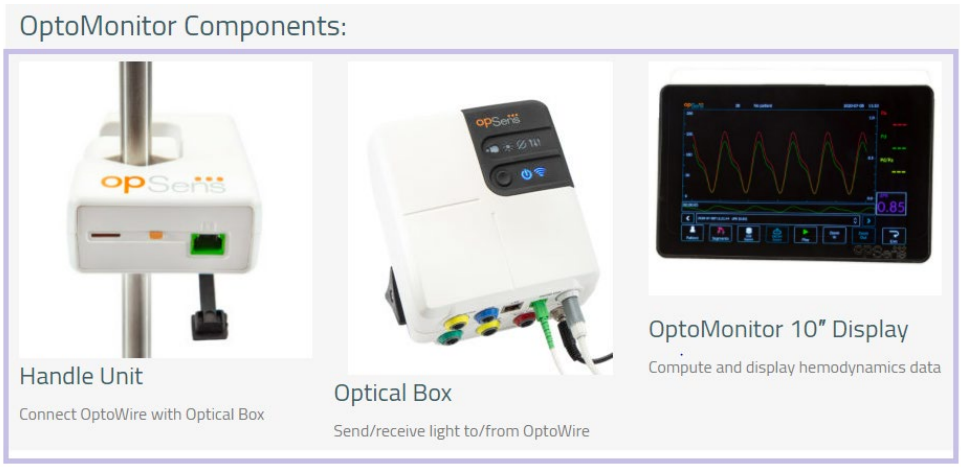
“The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system.”


</td></tr>
</table>

		https://opsensmedical.com/products/optomonitor/ "dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 5. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
11[d]	calculate a pressure ratio for a diagnostic window of a cardiac cycle of the patient, wherein a starting point of the diagnostic window is determined based on at	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to calculate a pressure ratio for a diagnostic window of a cardiac cycle of the patient, wherein a starting point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient, wherein the pressure ratio is calculated as an average of the received distal pressure measurements obtained during the diagnostic window divided by an

	least one of the received proximal pressure measurements or the received distal pressure measurements and an ending point of the diagnostic window is determined based on at least one of the received proximal pressure measurements or the received distal pressure measurements such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient, wherein the pressure ratio is calculated as an average of the received distal pressure measurements obtained during the diagnostic window divided by an average of the	average of the received proximal pressure measurements obtained during the diagnostic window. Exemplary public evidence includes:  https://opsensmedical.com/products/optomonitor/ <table><tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr><tr><td>dPR</td><td>Diastolic pressure ratio</td><td>Pd/Pa during the flat period of the dP/dt signal (the wave-free period)</td><td>Generic—Erasmus MC/ Rotterdam</td></tr></table> *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.

	received proximal pressure measurements obtained during the diagnostic window; and	 *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540 (annotation in original). "dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio). iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively. The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 6. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same

		ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
11[e]	output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient.	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient. Exemplary public evidence includes:   https://opsensmedical.com/products/optomonitor/

DPR	Diastolic pressure ratio	Average Pd/Pa during the entire diastole	Generic—Opsens, Acist (?)
dPR	Diastolic pressure ratio	Pd/Pa during the flat period of the dP/dt signal (the wave-free period)	Generic—Erasmus MC/ Rotterdam

https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.

<table>
<tr>
<td>26[pre]</td>
<td>A system for evaluating a stenosis of a vessel of a patient, the system comprising:</td>
<td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a system for evaluating a stenosis of a vessel of a patient. Exemplary public evidence includes the following excerpts from OpSens' website:

OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries.

OptoWire is powered by Fidela™, a patented 2nd generation fiber optic sensor to measure physiologic indices including Fractional Flow Reserve (FFR and diastolic Pressure Ratio (dPR).

▸ MORE INFORMATION

https://opsensmedical.com/products/optowire/

With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices:

<table>
<tr><th></th><th>FFR</th><th>Pd/Pa</th><th>cFFR</th><th>dPR</th></tr>
<tr><td>Valeur de coupure</td><td>0.80[1]</td><td>0.91[2]</td><td>0.83[3]</td><td>0.89[4]</td></tr>
<tr><td>Correlation vs FFR</td><td></td><td>81.5%[2]</td><td>85.8%[3]</td><td></td></tr>
<tr><td>Correlation vs iFR™</td><td></td><td></td><td></td><td>98%[4]</td></tr>
</table>
1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066

https://opsensmedical.com/products/optomonitor/

"5.6 INDICATIONS FOR USE

To measure pressure in blood vessels including both coronary and peripheral vessels, during diagnostic angiography and/or any interventional procedures. Blood pressure measurements provide hemodynamic information, such as fractional flow reserve, for the diagnosis and treatment of blood vessel disease."

OpSens Submission for FDA Approval, Complaint Exhibit C, p. 5.</td>
</tr>
<tr>
<td>26[a]</td>
<td>A pressure-sensing guide wire sized and</td>
<td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise A pressure-sensing guide wire sized and shaped for introduction into the vessel of</td>
</tr>
</table>

	shaped for introduction into the vessel of the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure monitoring element coupled to the distal portion;	the patient, the pressure-sensing guide wire comprising a proximal portion, a distal portion, and a pressure monitoring element coupled to the distal portion. Exemplary public evidence includes the following excerpts from OpSens' website:  "OptoWire OpSens OptoWire is a modern pressure guidewire designed to assess stenoses in vessels such as coronary arteries."  https://opsensmedical.com/products/optowire/ "The OptoWire III was then reconnected to the OptoMonitor and post-PCI physiology repeated with an increase in resting dPR to 0.97, indicating no residual

		flow limitation. The OptoWire III was withdrawn to the tip of the guide catheter, an absence of pressure drift confirmed, and the wire and guiding catheter removed. The patient was symptom-free and in stable condition at the procedure end." https://www.hmpgloballearningnetwork.com/site/cathlab/content/opsens-optowire-iii-next-generation-workhorse-pressure-guidewire
26[b]	A processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument, the processing unit configured to:	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise A processing unit in communication with the pressure-sensing guide wire and a pressure-sensing instrument. Exemplary public evidence includes the following excerpts from OpSens' website:  "The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system." With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices: FFR / Pd/Pa / cFFR / dPR Valeur de coupure: 0.80[1] / 0.91[2] / 0.83[3] / 0.89[4] Correlation vs FFR: 81.5%[2] / 85.8%[3] Correlation vs iFR™: 98%[4] 1 Tonino PA et al. Fractional flow reserve versus angiography for guiding percutaneous coronary intervention. N Engl J Med 2009;360:213-24 2 Jeremias, J Am Coll Cardiol, 2014; 3 Johnson N, et al. J Am Coll Cardiol Intv 2016;9:757–67; 4 Marcel van't Veer et al, J Am Coll Cardiol. 2017 Dec 26;70(25):3088-3096. doi: 10.1016/j.jacc.2017.10.066

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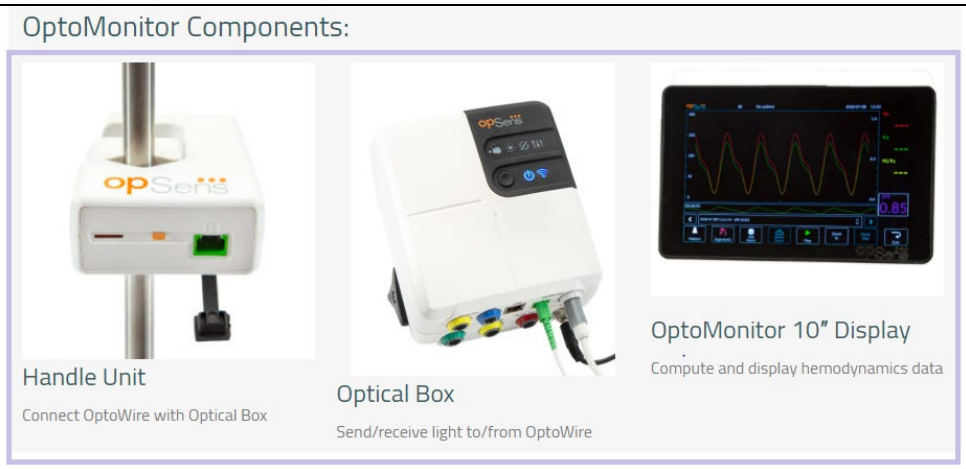
<tr><td></td><td></td><td> 

https://opsensmedical.com/products/optomonitor/</td></tr>
<tr><td>26[c]</td><td>Receive proximal pressure measurements obtained by the pressure-sensing instrument during a cardiac cycle of the patient, wherein the proximal pressure measurements are obtained without application of a hyperemic agent to the patient;</td><td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to receive proximal pressure measurements obtained by the pressure-sensing instrument during a cardiac cycle of the patient, wherein the proximal pressure measurements are obtained without application of a hyperemic agent to the patient. Exemplary public evidence includes the following excerpts from OpSens’ website:

<table>
<tr><td>DPR</td><td>Diastolic pressure ratio</td><td>Average Pd/Pa during the entire diastole</td><td>Generic—Opsens, Acist (?)</td></tr>
<tr><td>dPR</td><td>Diastolic pressure ratio</td><td>Pd/Pa during the flat period of the dP/dt signal (the wave-free period)</td><td>Generic—Erasmus MC/ Rotterdam</td></tr>
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“The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system.”</td></tr>
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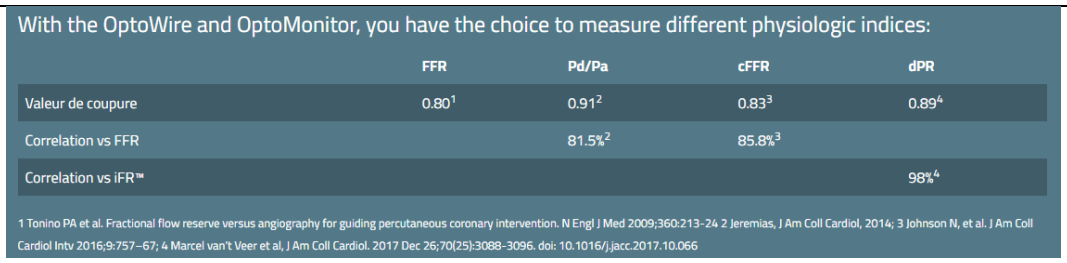


https://opsensmedical.com/products/optomonitor/

“dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio).

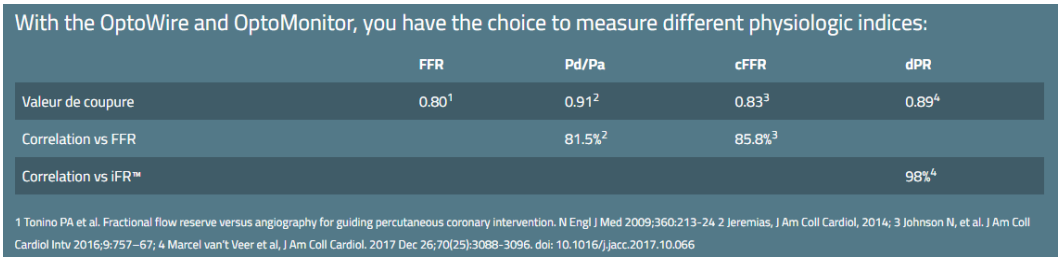
iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively.

The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping.”

Opsens Submission for FDA Approval, see Complaint Exhibit C at p. 5.

“dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device).”

Opsens Submission for FDA Approval, see Complaint Exhibit C at p. 7.
</td>
</tr>
<tr>
<td>26[d]</td>
<td>Receive distal pressure measurements obtained by the pressure monitoring</td>
<td>Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to receive distal pressure measurements obtained by the pressure monitoring element of the pressure-sensing guide wire during the cardiac cycle of the patient, wherein the distal pressure measurements are obtained</td>
</tr>
</table>

	element of the pressure-sensing guide wire during the cardiac cycle of the patient, wherein the distal pressure measurements are obtained without the application of the hyperemic patient to the patient;	without the application of the hyperemic patient to the patient. Exemplary public evidence includes the following excerpts from OpSens' website: 				
---	---	---	---
DPR	Diastolic pressure ratio	Average Pd/Pa during the entire diastole	Generic—Opsens, Acist (?)
dPR	Diastolic pressure ratio	Pd/Pa during the flat period of the dP/dt signal (the wave-free period)	Generic—Erasmus MC/ Rotterdam | *See* https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540. "The OptoMonitor™ system brings a variety of solutions to help you manage all measurements directly at the table side or by integrating physiology measurements into your hemodynamic system."  With the OptoWire and OptoMonitor, you have the choice to measure different physiologic indices: |	FFR	Pd/Pa	cFFR	dPR
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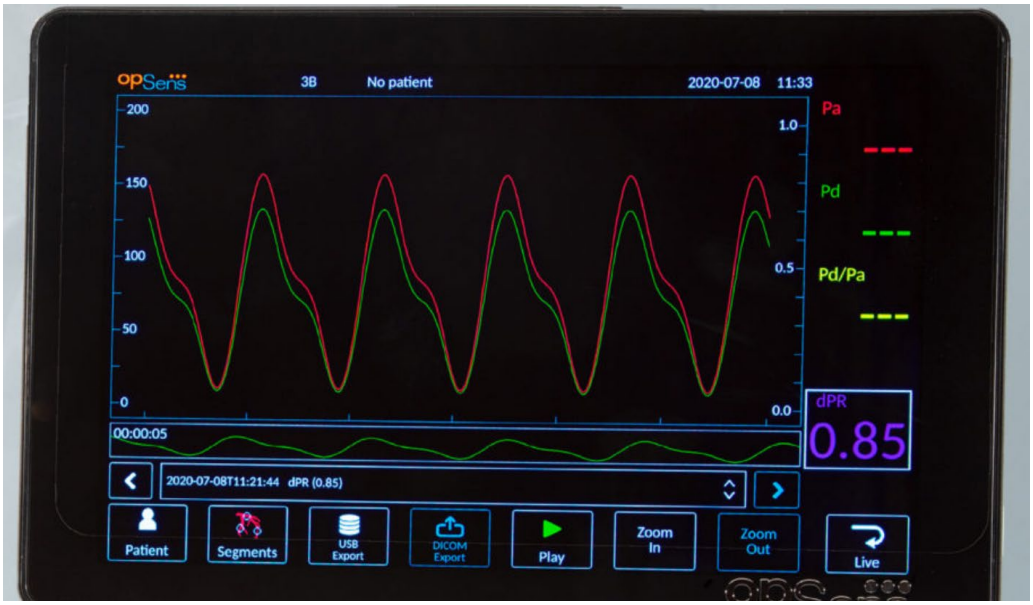
26[e]	Select a diagnostic window within the cardiac cycle of the patient such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient;	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to select a diagnostic window within the cardiac cycle of the patient such that the diagnostic window encompasses only a portion of the cardiac cycle of the patient. Exemplary public evidence includes the following excerpts from OpSens' website:  https://opsensmedical.com/products/optomonitor/

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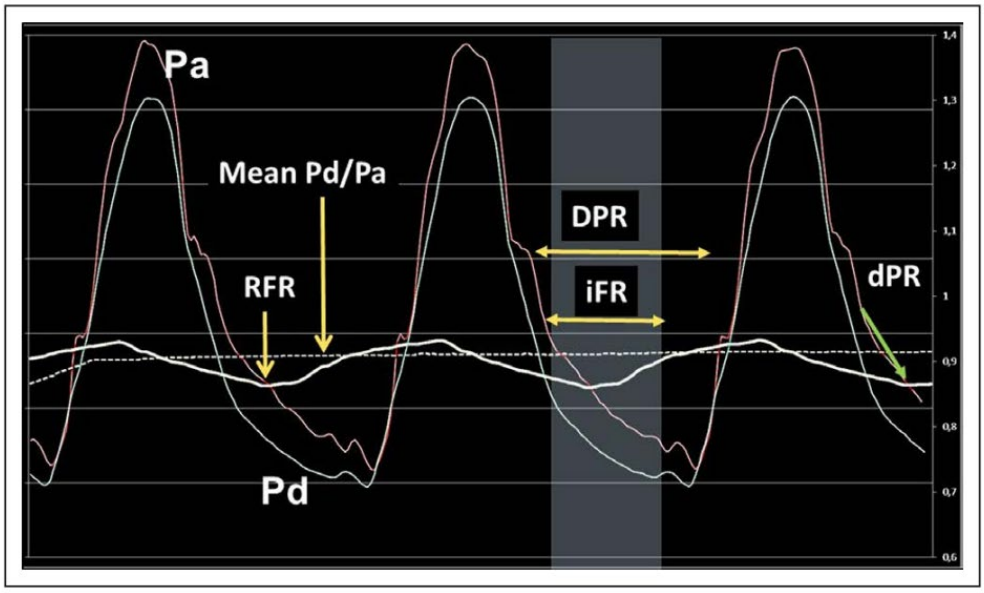

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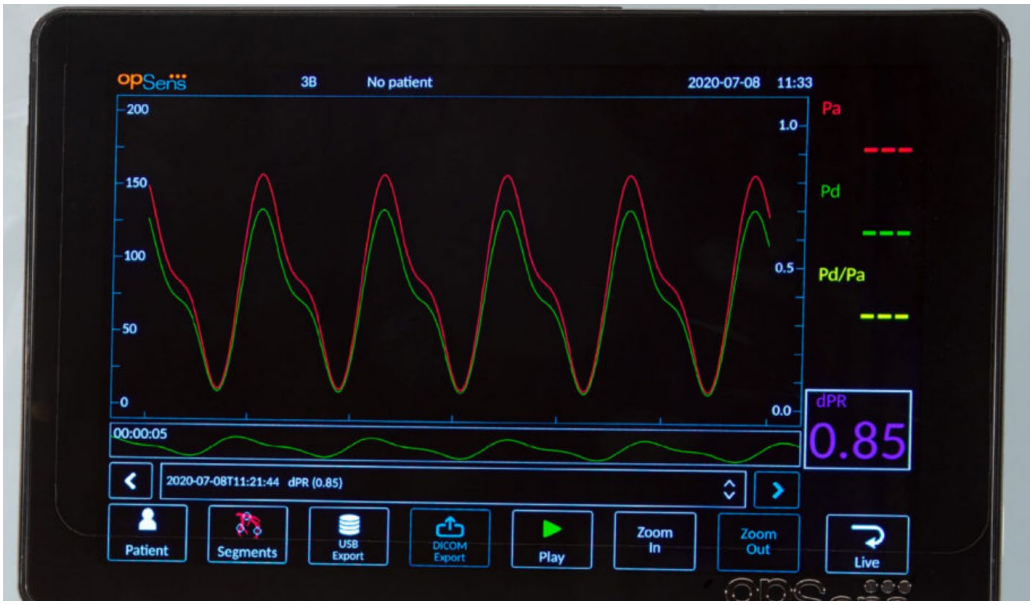
26[f]	Calculate a pressure ratio based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window, wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to calculate a pressure ratio based on a plurality of distal pressure measurements obtained during the diagnostic window and a plurality of proximal pressure measurements obtained during the diagnostic window, wherein the pressure ratio is calculated as an average of the plurality of distal pressure measurements obtained during the diagnostic window divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window. Exemplary public evidence includes the following excerpts from OpSens' website:  https://opsensmedical.com/products/optomonitor/

divided by an average of the plurality of proximal pressure measurements obtained during the diagnostic window; and		

DPR	Diastolic pressure ratio	Average Pd/Pa during the entire diastole	Generic—Opsens, Acist (?)
dPR	Diastolic pressure ratio	Pd/Pa during the flat period of the dP/dt signal (the wave-free period)	Generic—Erasmus MC/ Rotterdam

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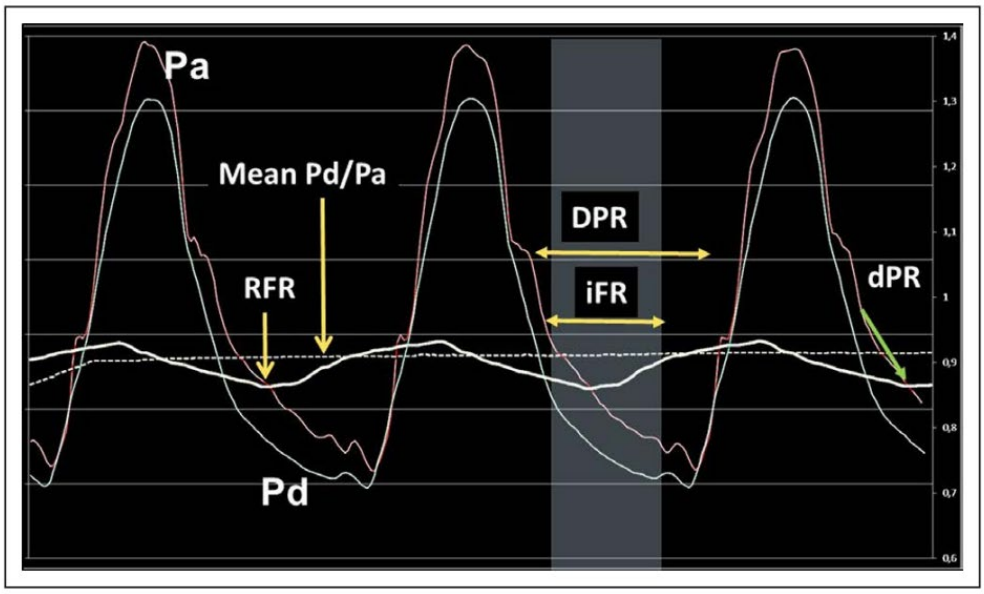

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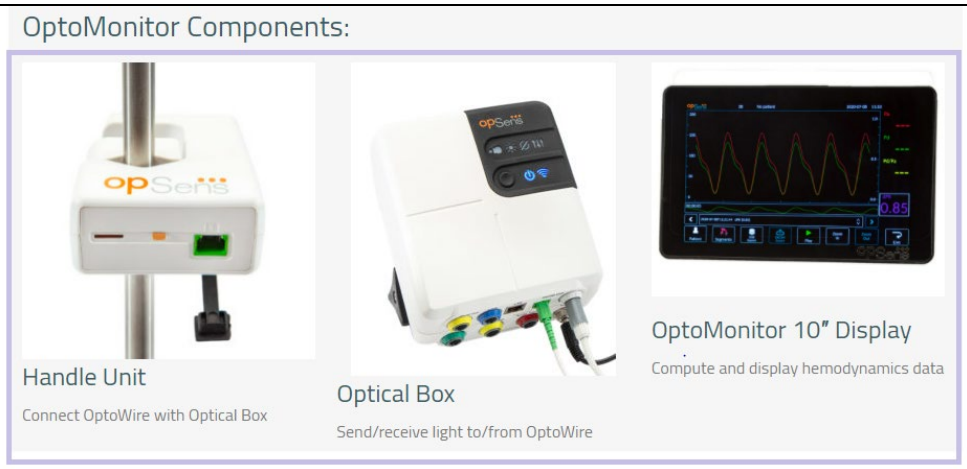
		different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 6. "dPR and iFR are resting indices used for the diagnostic of the severity of stenosis with the patient in resting condition, as opposed to inducing hyperemia when measuring FFR. dPR modality consists in calculating the ratio of Pd and Pa over the whole diastolic portion of the heart beat cycle while iFR calculate the same ratio over 75% of the diastole. Performance testing has confirmed equivalence of the proposed device to iFR (reference device)." *Opsens Submission for FDA Approval, see* Complaint Exhibit C at p. 7.
26[g]	Output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient.	Upon information and belief, the Accused Products, including at least the OptoMonitor, OptoWire, and accompanying auxiliary products, comprise a processing unit configured to output, to a display in communication with the processing unit, the calculated pressure ratio for evaluating the stenosis of the vessel without a hyperemic physiological effect on the patient. Exemplary public evidence includes the following excerpts from OpSens' website: 



https://opsensmedical.com/products/optomonitor/

DPR	Diastolic pressure ratio	Average Pd/Pa during the entire diastole	Generic—Opsens, Acist (?)
dPR	Diastolic pressure ratio	Pd/Pa during the flat period of the dP/dt signal (the wave-free period)	Generic—Erasmus MC/ Rotterdam

https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.118.007540.

"dPR is a resting index which consists in calculating the ratio of Pd and Pa over the diastolic portion of the heart beat cycle. dPR is a resting index for the diagnostic of the severity of stenosis equivalent to iFR (instantaneous wave-Free Ratio).

iFR calculates the ratio of Pd and Pa over 75% of the diastolic portion. The accuracy, specificity and sensitivity of dPR compared to iFR as a reference standard1 , using the same cut-off value of 0.89 and calculated from both CONTRAST2 and VERIFY 23 studies, are 97.1% [95.7%, 98.1% @95%CI], 95.9% [93.6%, 97.5% @95%CI] and 98.4 [96.6%, 99.3% @95%CI] respectively.

The diagnostic performance of dPR (cut-off=0.89) vs FFR (cut-off=0.80) compared to iFR (cut-off=0.89) vs FFR (cut-off=0.80) was also assessed. It was demonstrated that the diagnostic performance of dPR vs FFR is not statistically different from the diagnostic performance of iFR vs FFR, with 95% confidence interval significantly overlapping."

Opsens Submission for FDA Approval, see Complaint Exhibit C at p. 6.